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Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

For the protection of human subjects, the investigators have adhered to policies of applicable Federal Law 32 CFR 219 and 45 CFR 46.

Principal Investigator's Signature

6/18/01
Date

INTRODUCTION

This epidemiological study will investigate the hypothesis that Army personnel who reported medically unexplained physical symptoms (MUPS) to the Department of Veterans Affairs (VA) Persian Gulf Registry (PGR) or the Department of Defense (DoD) Comprehensive Clinical Evaluation Program (CCEP) upon returning from the Persian Gulf War have patterns of illness and medical care seeking during the year prior to deployment to the Persian Gulf that differ from those of comparison groups of Army personnel who deployed to the Persian Gulf who either did not sign up with either registry or did register but did not report MUPS. For members of each of these groups, investigators will abstract data from the military health records for the twelve months spent on active duty prior to Persian Gulf War deployment. Number and types of outpatient visits and inpatient stays will be compared.

The study is records-based and the end product will be an article submitted for publication in a peer-reviewed journal.

FIRST YEAR ACTIVITIES

During the first year of the project, the Medical Follow-up Agency (MFUA) of the Institute of Medicine (IOM) assigned staff to the data project and appointed seven experts to serve on an advisory panel. Considerable effort was spent, this first year, reviewing the predecessor pilot study and, in the light of lessons learned, revising the proposed study protocol. Staff sought and benefited from suggestions from the advisory panel, the MFUA board, the research subcommittee of the Military and Veterans Health Coordinating Board (of the Departments of Defense and Veterans Affairs), and others with expertise in the subject matter or the conduct of similar studies.

Current work focuses on finalizing study group selection criteria, a task requiring detailed understanding of—and access to—the VA and DoD registry databases and the literature on post-combat illnesses. Changes over time in the content and organization of registry data require that the investigators construct study group definitions that both account for the changing characteristics of the data systems and result in the best groups with which to explore the study hypotheses. This work is proceeding well. Based on prior experience and discussions with Army, VA, and Archives' staff, however, MFUA is concerned about a possible slowing of the project timetable. In the pilot study, after a full year its request for service health records, MFUA had received only 44 percent. Successful requests were limited almost entirely to those already within the VA system; the Army Reserve Personnel Command (ARPERSCOM) record management was backlogged and, during the course of the pilot, and was unable to fulfill any MFUA records requests. ARPERSCOM staff have indicated that the difficulties experienced during the pilot study should be ameliorated by that stage in this current study. If, however, ARPERSCOM has not yet transferred the service health records of the selected study group members to the VA Records Management Center—a real possibility—project completion would be accordingly delayed.

Staff. The assembled staff for this research project includes long-time veterans of MFUA projects in military and veterans health as well as promising newcomers (see Appendix A for staff listing). The core staff includes experience in epidemiology, military medicine, and database and computer programming, and VA, DoD, and NARA records.

Review of Pilot Study. Study staff reviewed the design and implementation of the pilot project upon which this full study is based. MFUA invited its pilot study collaborators—primarily, MAJ Eric Lund, M.D., and Han Kang, Ph.D., Director of VA's Environmental Epidemiology Service—to a series of meetings to clarify study population definitions and the logistics of selecting individuals from VA databases.

Human Subjects Clearance. A series of exchanges with the Human Subjects Protection Specialist (Ms. Catherine Smith), Regulatory Compliance and Quality, U.S. Army Medical Research and Materiel Command (USAMRMC) resulted in our receipt of Army notification of approval in letter dated October 4, 2000. The National Academy of Sciences Institutional Review Board earlier had reviewed the proposed research, granting initial approval on April 14, 1997, renewing that approval on July 5, 2000, and reiterating it in a September 28, 2000 letter to USAMRMC. This is records study only. Study groups will be selected from registries maintained by the VA and DoD, but the individuals will not be contacted at all. The analysis will involve data abstracted from military health records and registry-affiliated examination records. The results will be published in aggregate form with no identification of individuals.

Set Up Data Collection. Staff members (Dr. Thaul and Ms. Crawford) traveled to St. Louis, Missouri, to work out schedule and procedures with records administrators at the U.S. Army Reserve Personnel Command, VA Records Management Center, and the NARA National Personnel Records Center. For each of the numerous potential obstacles identified, staff worked with St. Louis personnel to set up alternative methods, scheduling courtesies, or problem-detection procedures. Staff also made logistical arrangements with a physician consultant for review of health record excerpts and coding according to study design.

Advisory Panel. MFUA staff, along with IOM leadership, consulted with people knowledgeable about military health care, Persian Gulf registries, post-deployment illnesses and symptoms, DoD and VA records access, and others to gather names of prospective advisory panel members. All seven individuals nominated accepted and the IOM president formally made the appointments. The advisory panel reflects academic and practical experience in military medicine and research, epidemiology, Persian Gulf War illnesses, veterans affairs, and clinical care (roster attached as Appendix A). The panel met with staff and invited guests, including DoD and VA representatives, on December 18, 2000 (agenda attached as Appendix B).

Communication with Experts. Staff presented the study design to various interested and knowledgeable groups for briefing and advice purposes. The MFUA board and the guests at its October 18–19, 2000 meeting and the Research Working Group (chaired by Jack Feussner) of the Military and Veterans Health Coordinating Board, on December 6, 2000, provided valuable suggestions.

Collaboration with Department of Veterans Affairs. MFUA has been working with the VA Environmental Epidemiology Service, a reservoir of Persian Gulf veteran-related data and related expertise, and is now formulating an official collaborative arrangement. This should allow for more and timely VA staff time.

Current. In addition to ongoing collection of resource documents and articles, the staff is at work with advisory panel members and VA researchers to explore—both conceptually and with data-based criteria—alternative case definitions.

PLANNED ACTIVITIES

In the coming months, with continued cooperation with the VA, MFUA will attempt to finalize basic study design, based on known administrative constraints (such as record availability), the status of data resources (relating to changes in VA and DoD data forms), and the suggestions of this project's advisory panel, the MFUA board, and the Military and Veterans Health Coordinating Board research subcommittee. Once that is achieved, subsequent tasks will be to:

- identify members of study population and request their relevant military records;
- process available records and seek to smooth search for seemingly unavailable records; and
- further plan analytic strategy.

There are no currently scheduled advisory panel meetings, but the investigators will consult with the panel before committing to a case definition. As the study progresses, the panel will meet to review data collection procedures and results and advise on data analysis and interpretation.

APPENDICES

A Advisory Panel and Staff Roster
B Panel Meeting Agenda (December 2000)

Annual Report for Contract DAMD17-00-C-0027
Submitted June 18, 2001 by
Susan Thaul, Ph.D., Study Director

APPENDIX A

INSTITUTE OF MEDICINE
The National Academies

Patterns of Illness and Care Before Deployment to the Persian Gulf War
Advisory Panel to Medical Follow-up Agency Class 3 Epidemiology Study

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Director, Medical Follow-up Agency

Pamela Ramey-McCray
Administrative Assistant

APPENDIX B

The Medical Follow-up Agency

Patterns of Illness and Care Before Deployment to the Persian Gulf War Advisory Panel

Agenda—First Meeting—18 December 2000

1055 Thomas Jefferson Street, NW • Washington, DC • Room FO 2003

9:30 AM	Continental breakfast in conference room
10:00 AM	Welcome, study background, and orientation to meeting *Susan Thaul*, Study Director, Medical Follow-up Agency
10:15 AM	Bias and conflict-of-interest discussion *Clyde Behney*, Deputy Executive Officer, Institute of Medicine
10:40 AM	Pilot study *MAJ Eric Lund*, Medical Corps, United States Army
11:15 AM	Full study design and overview of design concerns *Susan Thaul*
Noon	Working lunch (buffet provided in conference room)
1:00 PM	Design concerns *Susan Thaul* *Harriet Crawford*, Operations Manager, Medical Follow-up Agency • Identifying study groups • Acquiring military health records • Clarifying hypotheses and interpretive traps
3:00 PM	Break
3:15 PM	Discussion
5:00 PM	Adjourn